


Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB#0925-0753). Do not return the completed form to this address.

Filling out PDF Forms

This PDF form contains “**roll-over** or **double-click** ” help functionality.

This form allows you to enter data directly onto the screen. After completing the form, you are able to print the document so that you can fax/mail the document.

To fill out a form:

1. Select the hand tool. 
2. Position the pointer inside a field, and click to type text.
3. After entering text or selecting a check box, do one of the following:
 - Press tab to accept the form field change and go to the next form field.
 - Press Shift+Tab to accept the form field change and go to the previous form field.
 - Press Enter (Windows) or Return (Mac OS) to accept the form field change and deselect the current form field.
4. Once completed, print the form.

Cancer Trials Support Unit

Site Addition Form

(Utilized for the addition of a site to an existing IRB approval)

Email, Mail or Fax:
Cancer Trials Support Unit
ATTN: Coalition of Cancer Cooperative Groups
Suite 1100
1818 Market Street
Philadelphia, PA 19103 FAX: 1-215- 569 - 0206
CTSUSiteAddition@ctsucog.org

Submit to the CTSU Regulatory Office via the Regulatory Submission Portal: www.ctsu.org.

This form can be utilized when an IRB has added an additional site to an **existing** IRB approval.

- This form can be submitted in lieu of an IRB approval letter if signed by an IRB signatory.
- If not signed by an IRB signatory, an IRB approval letter must accompany this form.
- If the approval applies to multiple protocols, attach a supplemental list of protocols to this form.

1) Protocol #:		2) Protocol Title: <i>(Shortened version acceptable)</i>	
3a) Parent Institution Name <i>(List the name of the parent institution who has the current IRB approval):</i>		3b) Parent Institution NCI Code <i>(ALXXX):</i>	3c) Parent Institution FWA Assurance Number:
4a) New Institution Name(s) <i>(List the names of the new institutions being added to the parent institution's approval)</i>		4b) New Institution NCI Code <i>(ALXXX)</i>	4c) New Institution FWA Assurance Number:
5) Principal Investigator:		6) NCI Investigator #:	

This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations or subparts:

7) Approval Type: Initial or Renewal <input type="checkbox"/> Amendment <input type="checkbox"/>		8) Review Type: Full Board <input type="checkbox"/> Expedited <input type="checkbox"/>	
9) Date of IRB or Designee Review in box 7: / / m m d d y y y y		10) OHRP IRB Registration Number: IRB	

11) Comments:

The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed & certification will be provided. Questions #1 through #17 must be completed for this form to be accepted.
Check here if the person signing this form is an IRB signatory as documented on the institutional assurance with OHRP.

12) Name of IRB Signatory:		13) Name of approving IRB:	
14) Title of IRB Signatory:		15) Phone (____) _____ - _____	
16) Signature:		17) Date: / / m m d d y y y y	